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JOHN BOWER

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOHN BOWER,

Plaintiff,

v.

WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware corporation; and MICROPORT ORTHOPEDICS, INC., a Delaware corporation.

Defendants.

Case No. 2:17-cv-03178-CAS-KS

FIRST AMENDED COMPLAINT FOR DAMAGES

1. Strict Products Liability – Manufacturing Defect
2. Strict Products Liability – Failure to Warn
3. Negligence
4. Negligence – Failure to Recall/Retrofit
5. Fraudulent Misrepresentation
6. Fraudulent Concealment
7. Negligent Misrepresentation

DEMAND FOR JURY TRIAL

Plaintiff, John Bower, by and through his attorneys of record, Kiesel Law LLP, hereby files this Complaint for Damages and Jury Trial Demand against Defendants Wright Medical Technology, Inc., a Delaware corporation, MicroPort Orthopedics, Inc., a Delaware corporation, and DOES 1-10, to allege the following causes of action against Defendants, and each of them, as follows:

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NATURE OF THE ACTION

1. Defendants have known for several years that their hip replacement device – the PROFEMUR® Total Hip System with PROFEMUR® Stem (the "Stem") and PROFEMUR® Neck (the "Neck") (collectively referred to as "the PROFEMUR® Total Hip System" or "the Device") – was prone to fail within a few years of implantation despite the fact that hip implant devices typically last more than twenty years. The Stem and Neck of Defendants' Device is comprised of cobalt-chromium alloy. Defendants have long known that their Device has a tendency to fracture at the location of the highest tensile stress concentration in the Neck-Stem-body transition during even low to moderate physical activity. Significantly, consequent to reports of complaints of the defects in and fractures of the Device, Defendant MicroPort issued a voluntary recall and ceased marketing the Device. As a result of the Device's defects and Defendants' tortious acts/omissions, Plaintiff John Bower, and many other patients who received these devices, endured unnecessary pain and suffering; debilitating lack of mobility; and a subsequent more difficult revision surgery to replace the faulty Device, giving rise to more pain and suffering, prolonged recovery time, and increased risk of complications and death from surgery.

2. Plaintiff John Bower has suffered from unnecessary pain, debilitation, hospitalization, and the need to undergo subsequent revision surgery because Defendants defectively designed the Device and failed to adequately warn of the dangers of the Device.

PARTIES

3. Plaintiff John Bower (hereinafter "Plaintiff" or "Plaintiff John Bower") is, and all times relevant hereto was, a resident and citizen of Summit County, Utah. Plaintiff underwent a left total hip arthroplasty on October 1, 2013, at Cedars-Sinai Medical Center in Los Angeles, California. At that time, the PROFEMUR® Total Hip System manufactured, designed, distributed, labeled, marketed, and warranted

by Defendant Wright Medical Technology, Inc. was implanted into Plaintiff. Plaintiff's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgery. The PROFEMUR® Total Hip System implanted on Plaintiff's left side subsequently failed on December 4, 2016, and necessitated revision surgery. At the time of Plaintiff's revision surgery, Defendant MicroPort Orthopedics, Inc. manufactured, labeled, marketed, promoted, and distributed the PROFEMUR® Total Hip System.

4. Defendant Wright Medical Technology, Inc. (hereinafter "Wright" or "Wright Medical") is a corporation organized under the laws of the State of Delaware, with its principal place of business located in Memphis, Tennessee, and as such is a citizen of both the State of Tennessee and the State of Delaware. Defendant Wright is registered to do business in the State of Tennessee, and may be served with process by serving its registered agent for service, Corporation Service Company, at 2908 Poston Avenue, Nashville, Tennessee 37203-1312.

5. Defendant MicroPort Orthopedics, Inc. (hereinafter "MicroPort") is a corporation organized under the laws of the State of Delaware, with its headquarters and principal place of business located in Arlington, Tennessee, and as such is a citizen of the State of Tennessee and the State of Delaware. Defendant MicroPort is registered to do business in the State of Tennessee, and may be served with process by serving its registered agent for service, the C T Corporation System, at 800 S. Gay St., Suite 2021, Knoxville, Tennessee 37929-9710.

6. The true names or capacities, whether individual, corporate, associate, or otherwise of Defendants DOES 1 through 10, inclusive, and each of them, are unknown to Plaintiff who, therefore, sues said defendants by such fictitious names. Plaintiff is informed, believes, and thereupon alleges that each defendant designated herein by a fictitious name is in some manner legally responsible for the events and happenings herein referred to, and proximately caused foreseeable damages to Plaintiff as alleged herein. Plaintiff will seek leave of Court to amend this Complaint

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when the names of said DOE defendants are ascertained.

7. As used herein, "Defendants" includes all named Defendants and DOES 1-10, inclusive.

8. At all times relevant hereto, the Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third-parties or related entities, numerous prosthetic orthopedic products, including the PROFEMUR® Total Hip System.

9. At all times relevant hereto, the Defendants were also involved in the business of monitoring and reporting adverse events concerning the PROFEMUR® Total Hip System, and participated in the decision process and response, if any, related to these adverse events.

10. At all times relevant hereto, either directly or through their agents, apparent agents, servants, or employees, the Defendants sold, distributed, and marketed the defective PROFEMUR® Total Hip System in the State of California. Defendants derive substantial revenue from orthopedic products used or implanted in the State of California. As such, Defendants expected or should have expected that their business activities could or would subject them to legal action in the State of California.

11. At all times relevant hereto, each of the Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other and was acting within the scope of this respective authority by virtue of those interrelationships.

JURISDICTION AND VENUE

12. This Court has personal jurisdiction over the Defendants because each has sufficient minimum contacts with the State of California. At all times relevant hereto, Defendants directly or through their agents conducted regular and sustained business in California by selling and distributing their products in California, and

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engaged in substantial commerce and business activity in the County of Los Angeles.

13. Defendants derive substantial revenue from orthopedic products used or implanted in the State of California. Defendant Wright's website lists approximately 200 doctors in California, including more than 80 in the County of Los Angeles, who have used Defendant Wright's products. As such, Defendants expected or should have expected that their business activities could or would subject them to legal action in California.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the Parties are completely diverse in citizenship—Plaintiff is a Utah citizen and Defendants are citizens of both Tennessee and Delaware—and the amount in controversy exceeds $75,000.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) and (b)(2), as a substantial part of the events or omissions giving rise to this claim occurred in the County of Los Angeles. Plaintiff received the PROFEMUR® Total Hip System implant manufactured, designed, distributed, labeled, marketed, and warranted by Defendant Wright Medical Technology, Inc. at Cedars-Sinai Medical Center in Los Angeles. Defendants directly or through their agents represented to the medical and healthcare community in Los Angeles, including to Plaintiff's surgeon at Cedars-Sinai Medical Center, Jason Snibbe, M.D., that the PROFEMUR® Total Hip System had been properly tested and was safe and effective for its indicated use. Jason Snibbe, M.D. continues to regularly treat Plaintiff in Los Angeles for medical issues related to the failure of Plaintiff's PROFEMUR® Total Hip System implant.

STATEMENT OF FACTS

16. In December 1999, Wright acquired Cremascoli Ortho ("Cremascoli"), a European manufacturer of artificial hip devices which had designed and manufactured artificial hips with a modular neck component since approximately

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1985.

17. Pursuant to the Section 510(k) Premarket Notification Process ("510(k) Process"), on December 13, 2000, Wright received permission from the United States Food and Drug Administration ("FDA") to distribute in the United States its first modular neck and stem artificial hips – its PROFEMUR® Hip System, the Device at issue in the present litigation.

18. The Device the FDA permitted Wright to distribute by way of the510(k) Process included a modular neck component that had been designed and, since approximately 1985, had been distributed in Europe by Cremascoli.

19. The FDA never considered and approved the safety of the PROFEMUR® Total Hip System, but instead concluded only that the Device was substantially equivalent to an already legally marketed device, i.e., the Cremascoli modular neck device.

20. Sometime after December 13, 2000, Wright began to manufacture, label, market, promote, distribute, and sell in the United States the Wright Medical PROFEMUR® Hip System and its components, including the PROFEMUR® modular necks.

21. The Wright Medical PROFEMUR® modular necks that were distributed after December 13, 2000, and before August 25, 2009, were all made of a titanium-aluminum-vanadium alloy known as Ti6A14V.

22. On August 25, 2009, pursuant to a subsequent Section 510(k) Premarket Notification (No. K091423), the FDA permitted Wright to distribute and market a PROFEMUR® device manufactured from cobalt chrome alloy instead of Ti6A14V, concluding – without assessing the safety of the device – only that the cobalt chrome alloy device is "substantially equivalent" to the Ti6A14V device.

23. The Wright Medical PROFEMUR® modular necks, as promoted, marketed, distributed, and sold in the United States after December 13, 2000, for use with various Wright Medical hip systems, were manufactured in twelve models or

styles, six of those twelve were generally identified by Wright as "short" necks (i.e., Catalog #s PHA0-1202, PHA0-1212, PHA0-1222, PHA0-1232, PHA0-1242, and PHA0-1252), and six identified by Wright as "long" necks (i.e., Catalog #s PHA0-1204, PHA0-1214, PHA0-1224, PHA0-1234, PHA0-1244, and PHA0-1254).

24. In various marketing and promotional materials published and distributed by Wright from approximately the year 2002, and into the year 2005, and available to Wright's sales representatives and distributors, surgeons, patients, and the general public, Wright made the following representations, statements, claims, and guarantees about its PROFEMUR® modular necks:

> The modular neck used with the Profemur Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur Hip. None of the necks has experienced a clinical failure since their inception.
>
> [emphasis added]

and,

> The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:
>
> - Structural reliability
> - Absence of significant micromovement
> - Absence of fretting corrosion
>
> [emphasis added]

[Wright Medical Technical Monograph MH688-102 ©2004].

25. In 2001, Wright made a design change to its PROFEMUR® necks to increase the potential range of motion.

26. In making the 2001 design change to the PROFEMUR® modular necks, Wright changed the geometry, weight, and mass of the PROFEMUR® modular necks.

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27. More than 40,000 of the above-referenced modular necks "designed in 1985," and "successfully implanted in over 50,000 patients," and for which Wright claimed, "none of the necks has experienced a clinical failure since their inception," were of the original design that existed prior to the 2001 design change.

28. In fact, prior to the year 2001, Wright had received notice of clinical failures in the form of fractures of modular necks that had been implanted in patients in Europe.

29. In its initial 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright did not disclose to the FDA that it had notice of clinical failures in the form of modular neck fractures that had been implanted in patients in Europe.

30. Once Wright filed its 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright had a duty to report to the FDA any instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

31. Once Wright received permission to distribute PROFEMUR® modular necks in the United States as a result of its 510(k) Premarket Notification application, Wright had a duty to report to the FDA any instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

32. Prior to January of 2005, Wright knew or received notice of clinical failures in the form of fractures of its modular necks that had been implanted in patients in Europe.

33. Prior to April 19, 2005, Wright did not report to the FDA any of the instances it knew or received notice that a PROFEMUR® modular neck had clinically failed by the modular neck having fractured in a patient in Europe.

34. On or about April 19, 2005, Wright first reported to the FDA a PROFEMUR® modular neck clinical failure where the modular neck implanted in a

patient had fractured.

35. After receiving notice of the first modular neck fracture, Wright received notice of additional modular neck clinical failures in the form of modular neck fractures.

36. The number of PROFEMUR® modular neck clinical failures in the form of modular neck fractures have continued to increase over time, and continues to increase to the present day, now numbering more than 300 such clinical failures.

37. Fractures have been reported for both the long and the short versions of the PROFEMUR® modular necks.

38. The fracture rate for PROFEMUR® long modular necks is approximately eight times the fracture rate of the PROFEMUR® short modular necks.

39. The fracture rate for PROFEMUR® long modular necks implanted in the United States is more than 1% of the total number of PROFEMUR® long modular necks implanted in the United States.

40. Wright did not inform U.S. orthopedic surgeons known by Wright to have implanted the Device of any reports or concerns about fractures of its PROFEMUR® modular necks until a December 1, 2008, "Safety Alert" was sent to certain "medical professionals," which provided, in part, "[W]e have received reports of 43 modular neck failures as of November 21, 2008. Initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks and patient activities such as heavy lifting and impact sports."

41. At the time Wright sent its December 1, 2008, Safety Alert, Wright in fact was aware of more than 43 modular neck failures (by fracture of the modular neck).

42. In Wrights' Instructions for Use ("IFU") that accompanied the Device from their introduction into the United States, through 2008, if not later, Wright said that that the Device was contraindicated for use in obese patients, "[W]here obesity

is defined as three times normal body weight."

43. Prior to August 2010, Wright did not include a warning, precaution, or other advisory as to the use of any of its modular necks in people who weighed more than a specifically stated weight in its IFUs distributed in the United States.

44. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in heavyweight males in its IFUs distributed in the United States.

45. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in patients who engaged in heavy lifting in its IFUs distributed in the United States.

46. Prior to August 2010, Wright did not state that the use of any of its modular necks was contraindicated in patients who engaged in impact sports in its IFUs distributed in the United States.

47. Even though some Wright IFUs for Devices in use prior to August 2010 contained a section titled, "Conditions presenting increased risk of failure include," that section of the IFU did not state that patients weighing more than a certain weight, engaging in a high level of physical activity, engaging in heavy lifting, or engaging in impact sports, would be at an increased risk of failure (fracture) of the modular neck.

48. Even though some Wright IFUs for Devices in use prior to August 2010 contained a section titled "Warning," and a subsection within titled "Modular Necks," Wright did not state that patients weighing more than a certain weight, engaging in a high level of physical activity, engaging in heavy lifting, or engaging in impact sports, would be at an increased risk of failure (fracture) of the modular neck that subsection of the IFU.

49. Even though some Wright IFUs for Devices in use prior to August 2010 contained a section titled "General Product Information," that stated, "An overweight or obese patient can produce high loads on the prostheses, which can

lead to failure of the prosthesis," and, "If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation of the device, or both," Wright did not state that patients involved in an occupation or activity that included those activities created any higher risk of failure than would exist in any other design of artificial hip stem without a modular neck.

50. On or after August 25, 2009, Wright began distributing in the United States PROFEMUR® modular necks made of a cobalt chrome alloy.

51. PROFEMUR® modular necks distributed in the United States made of cobalt chrome are made in the same twelve sizes, versions and dimensions as the PROFEMUR® Ti6A14V modular necks.

52. Despite the change in materials, the PROFEMUR® cobalt chrome modular necks remain susceptible to micromotion and fretting corrosion at the neck-stem junction, similar to the otherwise identical model of PROFEMUR® Ti6A14V modular necks.

53. Despite the change in materials, the PROFEMUR® cobalt chrome modular necks continue to fail (fracture) at the neck-stem junction from cyclic loading and metal fatigue, similar to the otherwise identical model of PROFEMUR® Ti6A14V modular necks.

54. Notwithstanding Defendants' knowledge, until August 2015, Defendants had never directly informed patients in the United States who received the PROFEMUR® modular necks, and have not yet experienced a modular neck fracture, that the PROFEMUR® products have experienced higher than anticipated rates of failure due to fracture of the modular neck.

55. Notwithstanding Defendants' knowledge, Defendants have never informed patients in the United States who received the PROFEMUR® modular necks, and have not yet experienced a modular neck fracture, that higher weight and/or higher levels of activity may place patients at an increased risk and rate of

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failure due to fracture of the modular necks.

56. Notwithstanding Defendants' knowledge, Defendants had never directly asked their sales representatives/distributors or surgeons in the United States to directly inform any surgeons/patients who used/received these modular necks that patients of higher weight and/or higher levels of activity may be placed at an increased risk and rate of failure due to fracture of the modular necks.

57. Patient testimonials that have from time to time appeared on the Wright website and were available to Wright sales representatives/distributors, physicians, patients and the public from 2005 to the present, and/or that appeared in printed materials published by Wright from 2005 to the present, have represented that patients who received Wright artificial hips have already returned or are about to return to such activities as running, jogging, snow skiing, water skiing, marathon running, tennis, racquetball, golf, horseback riding, work that involves lifting and moving of heavy objects, active military duty in Iraq, karate, competitive wrestling and competitive motocross racing, among other activities.

58. Patient testimonials that have from time to time appeared on the Wright website, and in printed materials published by Wright from 2005 to the present, have been from men who received the Devices and weighed in excess of 250 pounds.

59. In 2014, Defendant MicroPort acquired Wright Medical's OrthoRecon Division, which was the hip division responsible for designing and selling PROFEMUR® modular necks.

60. On August 11, 2015, Defendant MicroPort announced a voluntary recall of the Long 8° Varus Cobalt Chrome Modular Neck, model PHAC-1254, in the interest of "patient safety".

61. The August 11, 2015, notice issued by MicroPort Chairman, Dr. Zhaohua Chang, reported that "[a]s of the date of [the] announcement, MicroPort Orthopedics [had] received 28 reports of implant failures" related to the cobalt

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chrome neck.

62. The subject of Defendant MicroPort's August 2015 recall is the exact cobalt chromium Wright PROFEMUR® modular neck implanted in Plaintiff John Bower.

63. Until the time of the device's recall, Defendant MicroPort continued to manufacture, label, market, promote, distribute, and sell in the United States the PROFEMUR® hip system and its components, including the PROFEMUR® modular necks.

64. On September 28, 2015, the FDA issued a Class 1 hip replacement recall of the PROFEMUR® Long Cobalt Chrome neck component, and advised patients to seek immediate medical treatment if they experience a sudden onset of severe pain in their post-operative hip.

PLAINTIFF JOHN BOWER'S PROFEMUR® DEVICE

65. Plaintiff John Bower brings this product liability personal injury action as a recipient of a defective medical device, i.e., a modular prosthetic hip, designed, manufactured, and distributed by Defendants.

66. On or about October 1, 2013, Plaintiff John Bower had left total hip arthroplasty, at which time he had the Device properly implanted by Jason Snibbe, M.D., at Cedars-Sinai Medical Center of Los Angeles, California. Specifically, Plaintiff received the PROFEMUR® "VV" Long neck, model PHAC-1254, made from cobalt chrome alloy.

67. Based upon the patient population that Defendants intended its PROFEMUR® hip systems to be implanted in and at the time Plaintiff John Bower had the Device implanted, he was an appropriate patient to be implanted with this hip system.

68. Subsequent to the date of implant, Plaintiff John Bower used his Device in a normal and expected manner.

69. On or about December 4, 2016, the femoral neck of the Device

suddenly and catastrophically failed, breaking into two pieces.

70. At the time of this catastrophic failure, Plaintiff John Bower was performing a normal and expected activity of daily living.

71. On December 4, 2016, following the catastrophic failure of the device, Plaintiff John Bower was taken to the St. Anthony Summit Medical Center emergency room in Frisco, Colorado, before he was transported to Porter Adventist Hospital in Denver, Colorado.

72. On December 6, 2016, Plaintiff John Bower's failed Device was surgically removed by Raymond Kim, M.D., at Porter Adventist Hospital in Denver, Colorado, in a surgical procedure commonly called a "revision".

73. At the time the Device was implanted in Plaintiff John Bower, it was in the same condition in all relevant respects as when it left Wright's control.

74. The PROFEMUR® Total Hip System (and its components) implanted in Plaintiff John Bower was not merchantable, but was unreasonably dangerous for its intended and/or reasonably foreseeable uses in that:

A. It was and is unreasonably dangerous as a result of one or more of a combination of the following:

(1) the neck was designed in such a manner as to be subjected to excessive micromotion and fretting corrosion, thereby increasing the potential for failure;

(2) the surface of the section of the neck that was inserted into the femoral stem was designed in such a manner as to increase the potential for fretting and corrosion and failure;

(3) the portion of the neck that was inserted in the femoral stem was in a narrow, confined space, thereby increasing the potential for fretting, corrosion and failure;

(4) the components were designed in such a way as to make the modular neck component susceptible to fretting and corrosion, thereby

increasing the potential for failure;

(5) the components were designed in such a way as to make the modular neck component susceptible to fatigue fractures;

(6) the risk of neck fracture outweighed the utility of the Device;

(7) a reasonably prudent manufacturer or seller, given knowledge of the Device's condition, would not have marketed or sold the Device; and

(8) there may be other conditions or defects yet to be determined.

B. It was dangerous to an extent beyond which would be contemplated by the ordinary consumer with the ordinary knowledge common to the community as to its characteristics in that:

(1) the ordinary consumer would not contemplate that the system would catastrophically fail within less than eight years after implantation; and

(2) the ordinary consumer would not contemplate that the ordinary activities of daily living would result in the system catastrophically failing within less than eight years after implantation.

75. The Device is not designed to withstand the normal activities of daily living after implantation without premature failure from fatigue fractures.

76. The Device is not designed to withstand the normal activities of daily living after implantation in active or heavier weight patients without premature failure from fatigue fractures.

77. The Device was not tested in design and development at the level of forces that were known would be encountered in the normal activities of daily living.

78. The Device was not tested in design and development at the level of forces that were known would be encountered in the normal activities of daily living of active or heavier weight patients.

79. The Device was not tested for the FDA Section 510(k) Premarket Notification Process at the level of forces that were known would be encountered in

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the normal activities of daily living.

80. The Device was not tested for the FDA Section 510(k) Premarket Notification Process at the level of forces that were known would be encountered in the normal activities of daily living of active or heavier weight patients.

81. The Device was not tested in design and development at the level of forces equal to the level of activities of patients that Wright promoted and marketed these devices to.

82. The Device was not tested for the FDA section 510(k) Premarket Notification Process at the forces equal to the level of activities of patients that Wright promoted and marketed these devices to.

83. The Device was known by Defendants to be failing from fatigue fractures of the modular necks prior to the date of its FDA section 510(k) Premarket Notification application.

84. The Device was known by Defendants to be failing from fatigue fractures of the modular necks prior to December 13, 2000, the date it received permission from the FDA to distribute these devices in the United States.

85. The Device was known by Defendants to be failing at higher than expected rates from fatigue fractures of the modular necks prior to the date of its implantation in Plaintiff John Bower.

86. The Device was known by Defendants to be failing at higher than expected rates from fatigue fractures of the modular necks prior to December 4, 2016, the date it fractured in Plaintiff John Bower.

87. Prior to the implant of the Device in Plaintiff John Bower, Wright did not warn patients, surgeons, customers, or its sales representatives/distributors that the Device was known to be failing from fatigue fractures at higher than expected rates.

88. Prior to the implant of the Device in Plaintiff John Bower, Wright did not warn patients, surgeons, customers, or its sales representatives/distributors that

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the Device was known to be failing from fatigue fractures in high activity or heavier weight patients at higher than expected rates.

89. Prior to the sudden catastrophic failure of Plaintiff John Bower's Device, Wright did not warn patients that the PROFEMUR® modular neck was known to be suddenly and catastrophically failing without warning from fatigue fractures during normal activities of daily living.

90. Prior to the sudden catastrophic failure of Plaintiff John Bower's Device, Wright did not warn patients that the PROFEMUR® modular neck was known to be suddenly and catastrophically failing without warning from fatigue fractures in high activity or heavier weight patients.

91. On or about December 4, 2016, the PROFEMUR® Total Hip System implanted in Plaintiff John Bower's left side catastrophically failed, i.e., fractured at the Neck, as a result of one or more or a combination of the foregoing unreasonably dangerous conditions.

92. As a direct and proximate result of the failure of the PROFEMUR® Total Hip System, Plaintiff John Bower has sustained injuries and damages including, but not limited to:

(a) undergoing surgery to remove and replace the failed prosthesis system;

(b) past and future pain and anguish, both in mind and in body;

(c) permanent diminishment of his ability to participate in and enjoy the affairs of life;

(d) medical bills associated with the replacement procedure and recovery therefrom;

(e) future medical expenses;

(f) loss of enjoyment of life;

(g) loss of past and future earnings and earning capacity;

(h) disfigurement; and

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(i) physical impairment.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT
(Against Wright)

93. Plaintiff repeats, re-alleges, and hereby incorporates by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

94. At all times relevant hereto, Wright designed, manufactured, distributed, sold, marketed, and promoted the PROFEMUR® Total Hip System that was implanted in Plaintiff on or about October 1, 2013.

95. At all times relevant hereto, the PROFEMUR® Total Hip System was expected to, and did, reach prescribing physicians and consumers, including Plaintiff John Bower and Plaintiff's physician, without a substantial change in the condition in which it was sold.

96. At all times relevant hereto, Plaintiff John Bower and Plaintiff's healthcare providers used the PROFEMUR® Total Hip System for its intended or reasonably foreseeable purpose.

97. At all times relevant hereto, the PROFEMUR® Total Hip System was dangerous, unsafe, and defective in manufacture. Such defects included, but were not limited to an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

98. Plaintiff John Bower is informed and believes, and thereupon alleges, that the PROFEMUR® Total Hip System implanted in Plaintiff was defectively manufactured because it differed from the manufacturer's design and specifications, or from typical units of the same product line.

99. As a direct, legal, proximate, and producing result of the defective manufacture of the PROFEMUR® Total Hip System implanted in Plaintiff John

Bower, Plaintiff sustained injuries as set forth above.

100. The dangerous, unsafe, and defective manufacturing of the PROFEMUR® Total Hip System implanted in Plaintiff John Bower was a substantial factor in causing Plaintiff's injuries as set forth above.

SECOND CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against All Defendants)

101. Plaintiff repeats, re-alleges, and hereby incorporates by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

102. The PROFEMUR® Total Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert the medical community and patients, including Plaintiff and Plaintiff's healthcare providers, to the dangerous risks associated with the PROFEMUR® Total Hip System when used for its intended and reasonably foreseeable purpose. The dangers and risks included, but were not limited to an unreasonably high propensity for corrosion, fretting, and fatigue under normal and expected use of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

103. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the PROFEMUR® Total Hip System for its intended or reasonably foreseeable purpose.

104. Plaintiff and Plaintiff's healthcare providers could not have discovered any defect in the PROFEMUR® Total Hip System through the exercise of due care.

105. Defendants knew or should have known, by the use of scientific knowledge available before, at, and after the time of manufacture, distribution, and sale of the PROFEMUR® Total Hip System, of potential risks and side effects associated with the PROFEMUR® Total Hip System. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said

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product, as previously set forth herein.

106. The warnings and instructions provided with the PROFEMUR® Total Hip System by Defendants did not adequately warn of the potential risks and side effects of the PROFEMUR® Total Hip System, which risks were known or scientifically knowable to Defendants.

107. Defendants had a continuing duty to warn the medical community and public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks and increased failure rate associated with the PROFEMUR® Total Hip System.

108. As a direct, legal, proximate, and producing result of Defendants' failure to warn, Plaintiff sustained injuries as set forth above.

109. Defendants' failure to adequately warn of the potential risks and side effects of the PROFEMUR® Total Hip System was a substantial factor in causing Plaintiff's injuries as set forth above.

THIRD CLAIM FOR RELIEF
NEGLIGENCE
(Against All Defendants)

110. Plaintiff repeats, re-alleges, and hereby incorporates by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

111. At all times relevant hereto, Defendants designed, manufactured, distributed, sold, marketed, and promoted the PROFEMUR® Total Hip System for implantation into customers, such as Plaintiff, by physicians and surgeons in the United States.

112. At all times relevant hereto, Defendants knew or should have known that the novel design of the PROFEMUR® Total Hip System necessitated clinical trials and other pre-marketing evaluations of risk and efficacy. Such testing would have revealed the increased risk of failure and complications associated with the PROFEMUR® Total Hip System. A reasonable manufacturer under the same and similar circumstances would have conducted additional testing and evaluation of the

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PROFEMUR® Total Hip System's safety and performance prior to placing the PROFEMUR® Total Hip System into the stream of commerce.

113. At all times relevant hereto, Defendants knew or should have known of the serious complications and high failure rate associated with the PROFEMUR® Total Hip System. Despite receiving hundreds of reports of serious complications from healthcare providers, Defendants chose (1) not to perform any additional testing of the PROFEMUR® Total Hip System; (2) not to investigate other potential causes of the complications; (3) not to suspend sales or distribution; and (4) not to warn physicians and patients of the PROFEMUR® Total Hip System's unreasonably high propensity for corrosions, fretting and fatigue under normal and expected used of the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

114. As a direct, legal, proximate, and producing cause of Defendants' negligent design, testing, manufacturing, marketing, selling, and promoting the PROFEMUR® Total Hip System, Plaintiff suffered injuries as set forth above.

115. Defendants' negligent design, testing, manufacturing, selling, and promoting the PROFEMUR® Total Hip System, was a substantial factor in causing Plaintiff's injuries as set forth above.

FOURTH CLAIM FOR RELIEF
NEGLIGENCE – FAILURE TO RECALL/RETROFIT
(Against All Defendants)

116. Plaintiff repeats, re-alleges, and hereby incorporates by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

117. At all times relevant hereto, Defendants knew or should have known that the design of the PROFEMUR® Total Hip System and its warnings were likely to be dangerous when used in an intended or reasonably foreseeable manner.

118. Despite the severity and number of complaints Defendants received, Defendants failed to recall, retrofit, or warn patients or physicians about the danger

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of the PROFEMUR® Total Hip System until August 2015.

119. Reasonable manufacturers, distributors, sellers, promoters, and designers under the same or similar circumstances would have recalled the PROFEMUR® Total Hip System earlier than August 2015.

120. As a direct, legal, proximate, and producing result of Defendants' failure to recall the PROFEMUR® Total Hip System earlier than August 2015, Plaintiff suffered injuries as set forth above.

121. Defendants' failure to recall the PROFEMUR® Total Hip System sooner was a substantial factor in causing Plaintiff's injuries as set forth above.

FIFTH CLAIM FOR RELIEF
FRAUDULENT MISREPRESENTATION
(Against All Defendants)

122. Plaintiff repeats, re-alleges, and hereby incorporates by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

123. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, that the PROFEMUR® Total Hip System had been properly tested and was safe and effective for its indicated use.

124. The representations made by Defendants to the medical and healthcare community and to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, regarding the safety and performance of the PROFEMUR® Total Hip System were, in fact, false.

125. Defendants knew or should have known that the PROFEMUR® Total Hip System had not been sufficiently tested, was defectively designed, and lacked adequate warnings and instructions.

126. Defendants knew or should have known that the PROFEMUR® Total Hip System could and would cause severe and grievous injury to users of said product, and that the PROFEMUR® Total Hip System's inherent dangers exceeded

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any purported, inaccurate, and/or downplayed warnings.

127. When said representations were made by Defendants, Defendants knew those representations to be false and exhibited a willful, wanton, and reckless disregard for the truth of said representations.

128. Said representations were made by Defendants with the intent to defraud and deceive Plaintiff, Plaintiff's healthcare providers, the medical community, and the general public. Defendants intended said representations to induce Plaintiff, Plaintiff's healthcare providers, the medical community and the general public, to recommend, implant, and/or purchase the PROFEMUR® Total Hip System for use as part of total hip replacement surgery. Defendants' actions evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

129. At all relevant times, Plaintiff and Plaintiff's healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

130. In reliance upon Defendants' representations, Plaintiff was induced and did use the PROFEMUR® Total Hip System, thereby sustaining severe and permanent personal injuries, and is now at an increased risk of sustaining severe and permanent personal injuries in the future.

131. Defendants brought the PROFEMUR® Total Hip System to the market, and acted fraudulently, wantonly, and maliciously to the detriment of Plaintiff.

132. As a direct, legal, proximate, and producing result of Defendants' false representations, Plaintiff suffered the injuries set forth herein.

SIXTH CLAIM FOR RELIEF
FRAUDULENT CONCEALMENT
(Against All Defendants)

133. Plaintiff repeats, re-alleges, and hereby incorporates by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

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134. Defendants knew their representations were false or recklessly disregarded the truth of said representations.

135. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, Defendants omitted, concealed or suppressed material information regarding the safety and performance of the PROFEMUR® Total Hip System, including, but not limited to:

(a) An unreasonably high propensity for corrosion, fretting and fatigue under normal and expected use for the device, leading to fracture of the modular neck and catastrophic failure of the device, requiring revision surgery.

(b) That the PROFEMUR® Total Hip System had an unacceptably high rate of failures requiring revision surgery;

(c) That the safety and performance of the PROFEMUR® Total Hip System was not adequately rested and/or known by Defendants;

(d) That patients implanted with the PROFEMUR® Total Hip System were at increased risk of experiencing painful and debilitating product failure and were more likely to undergo revision surgery than patients using other hip implant devices;

(e) The PROFEMUR® Total Hip System was designed, manufactured, marketed, promoted, distributed, and sold negligently, defectively, and/or improperly; and

(f) That safer alternatives were available.

136. Defendants purposefully downplayed and understated the serious nature of the risks associated with the use of the PROFEMUR® Total Hip System in order to increase and sustain sales.

137. Defendants had sole access to material facts regarding the safety and performance of the PROFEMUR® Total Hip System. Defendants know Plaintiff and Plaintiff's healthcare providers and/or the FDA had no way to determine the truth

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behind Defendants' concealment, omission, and suppression of material facts as set forth herein.

138. Plaintiff and Plaintiff's healthcare providers relied on Defendants' incomplete and inaccurate representations as to the safety and performance of the PROFEMUR® Total Hip System when selecting, recommending, and implanting the PROFEMUR® Total Hip System.

139. As a direct, legal, proximate, and producing result of Defendants' concealment of material facts, Plaintiff has suffered injuries as set forth herein.

SEVENTH CLAIM FOR RELIEF
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

140. Plaintiff repeats, re-alleges, and hereby incorporates by reference all of the allegations and statements contained in the preceding paragraphs as though fully set forth herein.

141. Defendants had a duty to truthfully represent to the medical community, and to Plaintiff, Plaintiff's healthcare providers, and the FDA, that the PROFEMUR® Total Hip System was properly tested and found to be safe and effective for its intended use.

142. Defendants knew or should have known that their representations regarding the safety and performance of the PROFEMUR® Total Hip System were, in fact, false.

143. Defendants failed to exercise ordinary care in determining the truth or falsity of their representations and by misrepresenting the safety and performance of the PROFEMUR® Total Hip System.

144. Defendants breached their duty to present truthful representations by knowingly, or by want of ordinary care, misrepresenting the safety and performance of the PROFEMUR® Total Hip System.

145. As a direct, legal, proximate, and producing result of Defendants' concealment of material facts, Plaintiff has suffered injuries as set forth herein.

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REQUEST FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and/or severally, as follows:

1. For general damages for personal injuries to Plaintiff, according to proof;
2. For all past, current, and future medical and incidental expenses, according to proof;
3. For all loss of earnings, present and future, and loss of earning capacity, according to proof;
4. For punitive and/or exemplary damages in an amount sufficient to punish Defendants and deter similar conduct in the future, according to proof;
5. For prejudgment interest, as provided by law;
6. For reasonable attorneys' fees;
7. For costs of litigation; and
8. For such other and further relief as this Court may deem just and proper.

Dated: April 4, 2018

Respectfully submitted,

KIESEL LAW LLP

By: /s/ Helen Zukin
Paul R. Kiesel
Helen Zukin
Jeffrey A. Koncius
Cherisse Heidi A. Cleofe

Attorneys for Plaintiff
JOHN BOWER

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

Dated: April 4, 2018

Respectfully submitted,

KIESEL LAW LLP

By: /s/ Helen Zukin
Paul R. Kiesel
Helen Zukin
Jeffrey A. Koncius
Cherisse Heidi A. Cleofe

Attorneys for Plaintiff
JOHN BOWER

KIESEL LAW LLP
Attorneys at Law
Beverly Hills, California

CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on April 4, 2018.

Respectfully Submitted,

KIESEL LAW LLP

By: /s/ Helen Zukin

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